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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,825

12/02/2005

Rachel Schneerson

4239-68226-07

1579

36218 7590 08/20/2008

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

08/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,825	Applicant(s) SCHNEERSON ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-22 and 34-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-22 and 34-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 May 2008 has been entered.

Claims 5 and 60 have been amended. Claims 54-62 have been correctly renumbered as claims 55-63.

2. Claims 1-6, 8-22, and 34-63 are pending and under consideration.

Objections or Rejections Withdrawn

3. The objection to claim 5 is withdrawn in light of the amendment of the claim.

4. The rejection of claims 1-6, 8-22, 34-46, and 49-63 under 35 U.S.C. 103(a) as being unpatentable over Alkan et al (*J. Immunology*, 107(2):353-358, 1971) and Welkos et al (*Microbiol.*, 147:1677-1685, 2001) in view of Pozsgay et al (*Proc. Natl. Acad. Sci., USA*, 96:5194-5197, 1999), is withdrawn in light of applicants' arguments.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6, 8-22, and 34-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1645

Claim 1 is drawn to an immunogenic conjugate comprising a synthetic homopolymer of γ PGA polypeptide covalently linked to a carrier, wherein the conjugate elicits an immune response in a subject.

It is unclear what the metes and bounds of the claim is because the only requirement of the conjugate is that it elicit an immune response in a subject. There is no requirement that the immune response be to the γ PGA. The immune response may be to the carrier moiety. Clarification is required concerning the identity of the immune response.

Claims 2-6, 8-22, 47-53, 57-58, and 62-63 depend from claim 1, but do not clarify the issue.

Claim 34 is drawn to an immunogenic conjugate comprising a *Bacillus* of γ PGA polypeptide covalently linked to a carrier, wherein the conjugate elicits an immune response in a subject.

It is unclear what the metes and bounds of the claim is because the only requirement of the conjugate is that it elicit an immune response in a subject. There is no requirement that the immune response be to the γ PGA. The immune response may be to the carrier moiety. Clarification is required concerning the identity of the immune response.

Claims 35-46, 54-56, and 59-60 depend from claim 34, but do not clarify the issue.

Claim 61 is drawn to an immunogenic conjugate comprising γ PGA polypeptide covalently linked to a carrier, wherein the conjugate elicits an immune response in a subject.

It is unclear what the metes and bounds of the claim is because the only requirement of the conjugate is that it elicit an immune response in a subject. There is no requirement that the immune response be to the γ PGA. The immune response may be to the carrier moiety. Clarification is required concerning the identity of the immune response.

Art Unit: 1645

Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisors, Shannon Foley (571)272-0898, and Robert B. Mondesi (571)272-0956.


The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 3, 2008

<i>Application Number</i> 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/559,825	SCHNEERSON ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	